January 2017– SUPPORT Summary of a systematic review

What are the effects of written information about medicines for consumers?

Medicines are the most common intervention used in most health systems. As with any treatment, patients need sufficient information to make informed decisions about their use. Written information, such as leaflets or online information, is the most common way of providing this information.

Key messages

➔ **Written medicine information may slightly improve knowledge and attitudes about medicines compared with no written information.**

➔ **Written medicine information may lead to little or no difference in adherence to instructions compared with no written information.**

➔ **The effect of written medicine information on health outcomes is uncertain. The review did not find studies that evaluated this.**

➔ **Written medicine information delivered in an 'easy-to-read' format compared with a standard manufacturer's format may lead to little or no difference in knowledge about and behaviours related to medicines, but it may slightly improve attitudes towards the information presented.**

➔ **Written numerical information about the risks of medicines may slightly improve knowledge and attitudes about medicines compared with the same information as text.**

➔ **The effects of written medicine information are mediated by the ability to read the information presented. Low literacy levels in low-income countries could make these findings less applicable.**

Who is this summary for?

People making decisions concerning patient information and pharmaceutical policies

! This summary includes:

- **Key findings** from research based on a systematic review
- **Considerations about the relevance of this research** for low-income countries

X Not included:

- Recommendations
- Additional evidence not included in the systematic review
- Detailed descriptions of interventions or their implementation

This summary is based on the following systematic review:

Nicolson DJ, Knapp P, Raynor DK, Spoor P. Written information about individual medicines for consumers. Cochrane Database Syst Rev 2009; 2: CD002104.

What is a systematic review?

A summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise the relevant research, and to collect and analyse data from the included studies

SUPPORT was an international project to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low- and middle-income countries, funded by the European Commission (FP6) and the Canadian Institutes of Health Research.

Glossary of terms used in this report: www.supportsummaries.org/glossary-of-terms

Background references on this topic: See back page

Background

In order to make informed decisions about the use of medicines, people taking them need good quality information. This information could be provided through written leaflets accompanying prescribed and over-the-counter medicines or written information available on the internet.

How this summary was prepared

After searching widely for systematic reviews that can help inform decisions about health systems, we have selected ones that provide information that is relevant to low-income countries. The methods used to assess the reliability of the review and to make judgements about its relevance are described here: www.supportsummaries.org/how-support-summaries-are-prepared/

Knowing what's not known is important

A reliable review might not find any studies from low-income countries or might not find any well-designed studies. Although that is disappointing, it is important to know what is not known as well as what is known.

A lack of evidence does not mean a lack of effects. It means the effects are uncertain. When there is a lack of evidence, consideration should be given to monitoring and evaluating the effects of the intervention, if it is used.

About the systematic review underlying this summary

Review objective: To assess the effects of providing written information about prescribed and over-the-counter medicines on patient outcomes

Types of	What the review authors searched for	What the review authors found
Study designs & Interventions	Randomised trials, non-randomised trials, controlled before-after and interrupted time series studies in which the effects of written information were compared with a control group or alternative intervention	25 randomised trials were included.
Participants	Patients of any age receiving written information about a prescribed or over-the-counter medicine in any setting (hospital in- and out-patients and primary care)	4788 participants were enrolled in the included trials. 19 studies involved patients with chronic conditions (using NSAIDs or cardiovascular medicines), 5 trials were focused on patients with acute conditions, and 1 on both.
Settings	Any setting	The trials were conducted in 9 countries: USA (8 trials), UK (8), Belgium (2), Canada (2), Finland (1), France (1), Hong Kong (1), Switzerland (1) and Turkey (1).
Outcomes	Patient knowledge about the medicine, patients' attitudes towards taking the medicine, patients' medicine-taking behaviour, and patients' health outcomes	Patients' knowledge: recall of information about the medicine, recall of side effects; patients' attitudes towards taking medicines; and patients' medicine-taking behaviour

Date of most recent search: March 2007

Limitations: This review had important limitations related to the assessment of the risk of bias for included studies and the analysis of heterogeneity. Additionally, it has not been updated since 2007.

Nicolson DJ, Knapp P, Raynor DK, Spoor P. Written information about individual medicines for consumers. Cochrane Database Syst Rev 2009; 2: CD002104.

Summary of findings

The review included 25 trials. All of them were conducted in high-income countries except for one carried out in Turkey. The two comparisons assessed by the review are detailed below.

There was an important variation in the content of the interventions used in the included trials, but most of the interventions (19 trials) included information about 'What this medicine is and what it is used for' and 'Possible side effects'.

The outcomes assessed were measured with many different methods. For instance, measures of knowledge and satisfaction were often developed for individual trials and appeared to be measuring different components of those outcomes.

1) Written medicine information versus no written information

Twenty trials assessed this comparison: 12 of them compared written medicine information to no information and in the other 8 trials both groups were given additional verbal information. Seventeen of the 20 trials measured a change in knowledge, 3 a change in attitudes, and 8 assessed a behavioural outcome.

➔ **Written medicine information may slightly improve knowledge and attitudes about medicines compared with no written information. The certainty of this evidence is low.**

➔ **Written medicine information may lead to little or no difference in the adherence to instructions compared with no written information. The certainty of this evidence is low.**

➔ **The effect of written medicine information on health outcomes is uncertain. There were no studies that evaluated the impact of written medicine information on health outcomes.**

About the certainty of the evidence (GRADE) *

⊕⊕⊕⊕
High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕◯
Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕◯◯
Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕◯◯◯
Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This is sometimes referred to as 'quality of evidence' or 'confidence in the estimate'.

† Substantially different = a large enough difference that it might affect a decision

See last page for more information.

Written medicine information compared to no written information		
People	People taking medicines for acute and chronic conditions	
Settings	Hospital and primary care in middle- and high-income countries	
Intervention	Written medicine information	
Comparison	No written medicine information	
Outcomes	**Impact**	Certainty of the evidence (GRADE)
Knowledge about the medicine and its side effects (measured with different instruments)	Findings were mixed, although most studies measuring knowledge found that either the written medicine information increased knowledge (recall of information or recall of side effects) or made little or no difference	⊕⊕◯◯ Low
Attitudes towards the information provided (scales of satisfaction with the information provided)	In 1 trial assessing attitudes regarding the usefulness and ease of comprehension of the written medicine information, there were differences favouring the intervention group. In the other 2 trials participants given written medicine information expressed greater satisfaction with the information provided.	⊕⊕◯◯ Low
Behaviour (self-reported adherence scales and biological markers of adherence)	In the trials examining adherence to instructions, adherence was higher among people given written medicine information. However, little or no difference was found when biological markers were used to assess adherence.	⊕⊕◯◯ Low
Health outcomes	No studies assessed this outcome	-
GRADE: GRADE Working Group grades of evidence (see above and last page)		

2) Different presentations of written medicine information

Eight trials compared the effect of presenting written medicine information in different ways. The comparisons assessed included 'easy-to-read' leaflets versus standard manufacturer's leaflets, numerical versus text descriptions of risks, and the order of presentation of the information (benefits and risks). Five of the studies measured a knowledge outcome, 4 an attitudinal outcome, and 2 assessed behaviour change. Because of the diversity of comparisons it was not possible to prepare a single Summary of Findings table for this group of comparisons.

➔ **Written medicine information delivered in an 'easy-to-read' format compared with a standard manufacturer's format may lead to little or no difference in knowledge or behaviours related to medicines, but it may slightly improve attitudes towards the information presented. The certainty of this evidence is low.**

➔ **Written numerical information about risks may slightly improve knowledge and attitudes about medicines compared with the same information as text. The certainty of this evidence is low.**

Relevance of the review for low-income countries

➔ Findings	▷ Interpretation*
APPLICABILITY	
➔ **All the trials – except one conducted in Turkey – were carried out in high-income countries.**	▷ *Implementation of written medicine information depends on the health systems' regulatory context. For instance in high-income countries there are specific laws that already govern the use of written medicine information. The implementation and impact in low-income countries without similar laws could be different from the findings from this review.* ▷ *The effects of written medicine information are mediated by the ability to read the information presented. Low literacy levels in a country could make these findings less applicable.*
EQUITY	
➔ **Overall, the review provides little data regarding differential effects of the interventions for disadvantaged populations.**	▷ *Interventions requiring skills unequally distributed in the population (such as reading) could increase inequalities regarding information about medicines and other health issues.* ▷ *In order to avoid an increase in inequalities, the design of the intervention should consider the level of literacy in the countries where the intervention is planned to be implemented.*
ECONOMIC CONSIDERATIONS	
➔ **There was no information about the cost or cost-effectiveness of the interventions**	▷ *Although the cost of scaling up the intervention could be affordable (written materials are relatively inexpensive), costs will depend on the regulatory context of the specific health system in which the intervention is implemented.*
MONITORING & EVALUATION	
➔ **The certainty of the available evidence is low and no evidence was found for some comparisons and outcomes.**	▷ *Consideration should be given to monitoring and evaluating the effects of changes in policies regarding the provision of information about medicines to patients on knowledge and behaviours. Randomised trials or interrupted time series studies should be used to evaluate the effects of changes in these policies when there is important uncertainty about the effects.*

*Judgements made by the authors of this summary, not necessarily those of the review authors, based on the findings of the review and consultation with researchers and policymakers in low-income countries. For additional details about how these judgments were made see: www.supportsummaries.org/methods

Additional information

Related literature

Ciciriello S, Johnston RV, Osborne RH, et al. Multimedia educational interventions for consumers about prescribed and over-the-counter medications. Cochrane Database Syst Rev 2013; 4: CD008416.

Ryan R, Santesso N, Lowe D, et al. Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews. Cochrane Database Syst Rev 2014; 4: CD007768.

This summary was prepared by

Tomás Pantoja, Unit of Health Policy & Systems Research, School of Medicine, Pontificia Universidad Católica de Chile, Chile.

Conflict of interest

None declared. For details, see: www.supportsummaries.org/coi

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This review should be cited as

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The summary should be cited as

Pantoja T. What are the effects of written information about medicines for consumers? A SUPPORT Summary of a systematic review. January 2017. www.supportsummaries.org

About certainty of the evidence (GRADE)

The "certainty of the evidence" is an assessment of how good an indication the research provides of the likely effect; i.e. the likelihood that the effect will be substantially different from what the research found. By "substantially different" we mean a large enough difference that it might affect a decision. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the study design (randomised trials versus observational studies), factors that reduce the certainty (risk of bias, inconsistency, indirectness, imprecision, and publication bias) and factors that increase the certainty (a large effect, a dose response relationship, and plausible confounding). For each outcome, the certainty of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

For more information about GRADE: www.supportsummaries.org/grade

SUPPORT collaborators:

The Cochrane Effective Practice and Organisation of Care Group (EPOC) is part of the Cochrane Collaboration. The Norwegian EPOC satellite supports the production of Cochrane reviews relevant to health systems in low- and middle-income countries . www.epocoslo.cochrane.org

The Evidence-Informed Policy Network (EVIPNet) is an initiative to promote the use of health research in policymaking in low- and middle-income countries. www.evipnet.org

The Alliance for Health Policy and Systems Research (HPSR) is an international collaboration that promotes the generation and use of health policy and systems research in low- and middle-income countries. www.who.int/alliance-hpsr

Norad, the Norwegian Agency for Development Cooperation, supports the Norwegian EPOC satellite and the production of SUPPORT Summaries. www.norad.no

The Effective Health Care Research Consortium is an international partnership that prepares Cochrane reviews relevant to low-income countries. www.evidence4health.org

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